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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/694,068 | 10/27/2003 | Donald W. Howie | 0103-0035(ZM0476) | 3820 |

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-------------------------------|--|------------------------------|--|
| Application No. 10/694,068 | | Applicant(s) HOWIE ET AL. | |
| Examiner Bruce E. Snow | | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-15,17,18 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 3,5-10,15,17,18 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed May 06, 2005, have been fully considered and the Examiner's position is believed adequately explained in the grounds of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3, 5-10, 17, 18, and 25-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 3 and 17-18, the femoral canal is positively claimed in the body of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable the "a third member projection from one of the first

and second members"; it only extends from the first member; this is broader than the scope of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5-10, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the scope and state of the claim is ambiguous. Line 14 claims "a cured cement mantel surrounding the stem," however, the positioner in line 15 is "removably engageable with the stem" and line 12, "implant to subside distally along the canal axis into a cured cement mantel under load". How is the positioner removed from cured cement and how does the stem subside into the cured cement? Please direct to the specification for support and a description. Note that the cured cement is positively claimed. Similar for claim 18, what state is the hip system being claimed? The preamble states "for implantation in a hip joint" wherein the body claims it in an implanted state.

Allowable Subject Matter

Claims 11-14 are allowed over the art of record.

Claims 25-26 contain allowable subject matter.

As far as the scope of the claims can be determined, the following is made of record.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Mathys, Sr. et al.

Mathys, Sr. et al teaches a positioner for implantation adjacent a femoral hip implant for retaining the femoral hip implant in a femoral canal having a canal wall, the positioner comprising:

means for preventing the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant down into the femoral canal (retension member, first member), see screw head; and means for anchoring the means for preventing relative to the femoral canal (anchor member, second member), see screw 9.

Regarding at least claim 15, the screw head extends in a direction perpendicular to the second member 9.

Claims 1 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter et al (5,425,768).

Carpenter et al teaches a positioner for implantation adjacent a femoral hip implant for retaining the femoral hip implant in a femoral canal having a canal wall, the positioner comprising:

means for preventing the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant down into the femoral canal Including elements 46 which couples to the stem 22 of the femoral hip implant; and

means for anchoring the means for preventing relative to the femoral canal 62 which are capable of being wedged in the femoral canal providing anchoring and further provide a "means for anchoring" once the cement cures.

Regarding the means for spacing, see element 48.

Regarding claim 24, note 3:2 et seq. teaching that the implant and positioner are inserted into the cement.

Regarding the new limitation to claim 1, "the implant to subside distally along the canal axis into a cured cement mantel", it is the Examiner's position that under a very large load, the device of Carpenter et al would fulfill this limitation.

Claims 15 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Link et al (4,698,063).

Link et al teaches a positioner for implantation adjacent a femoral hip implant for retaining the femoral hip implant in a femoral canal having a canal wall, the positioner comprising:

means for preventing the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant down into the femoral canal Including elements 10 and serrations;

and means for anchoring the means for preventing relative to the femoral canal 13 and the other serrations the stem.

Regarding claim 15, second members 13 are "at an angle" relative the concave wall surface of the first member 10.

Claim 22, elements 13 and 10 form a symmetrical "L" shape. The preamble does not limit additional elements.

Claims 15, 18, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Spotorno et al (2002/005266).

Spotorno et al teaches first member 8, 7 extending over the implant which limits upward movement of the implant and permits downward axial movement; and a second member 6 extending at an angle from the first member for anchoring.

Regarding claim 22, "L" shaped, multiple elements 7 all form an L shape with element 6. All legs 7 extend "over" the exterior of the implant and portions extend proximal the shoulder of the implant.

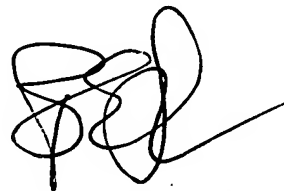
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER